HFI-35 3/20/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
- D1232B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER

March 3, 1997 WL-14-7

Richard A. Wesson, Ph.D.
Chief Operating Officer
Sunquest Information Systems
4801 East Broadway Boulevard
Tucson, AZ 85711

Dear Mr Wesson:

During an inspection of your manufacturing facility conducted between February 10 to 14, 1997, our investigators determined that your firm manufactures computer software for use by blood establishments. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to implement and verify solutions to quality assurance problems [21 CFR 820.20(a)(3)]. For example, our investigation disclosed that representatives of your quality assurance program made recommendations to correct software defects which were not been implemented in a timely manner. Specifically, our investigation determined that some quality assurance recommendations suggesting corrections to your computer software are upwards to two years old and have not been implemented. Our investigation also disclosed that two of the complaints leading to your quality assurance recommendations resulted in your firm issuing "Product Safety Notices" to your customers regarding possible software problems. Our investigation also disclosed that your firm has not been conducting risk assessments of complaints in a timely manner as directed by your written procedures.

2. Failure to investigate the failure of a device to meet any of its performance specifications after the device has been released for distribution and to make a written record of the investigation including conclusions and follow-up [21 CFR 820.162]. For example, our investigation disclosed that no investigation was conducted to ascertain why your validation test plan for a software upgrade passed your in house testing but failed at a user site.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612.

Sincerely yours,

Elaine C. Messa

Elaine C. Messa
District Director